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Can at-home semi-quantitative pregnancy tests serve as a replacement for clinical follow-up of medical abortion? A US study☆

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Abstract

Background: Medical abortion in the United States requires clinic-based follow-up, representing additional time and cost to women and clinics. We studied a semi-quantitative home pregnancy test as a possible replacement for in-person follow-up.
Study Design: Four hundred and ninety women participated in the clinical study and used a pregnancy test to determine baseline human chorionic gonadotropin (hCG) on the day of mifepristone administration and follow-up hCG 1 week later. One hundred and eighty-nine other women completed a user comprehension survey. Accuracy, feasibility and acceptability of the test were assessed in both the clinical study and the survey.
Results: The test identified the one ongoing pregnancy in the clinical study cohort. Sensitivity and specificity were calculated at 100.0% and 97.0%. The majority of participants in both the clinical study and the user comprehension survey found the test to be "very easy" or "easy" to use.
Conclusion: At-home follow-up with a semi-quantitative pregnancy test is feasible for service delivery in the United States.

Keywords: Medical abortion; Semi-quantitative pregnancy test; Human chorionic gonadotropin (hCG)

1. Introduction

Current clinical practice in US health care facilities requires women to return for clinic-based follow-up care after medical abortion. This visit is used primarily to determine if the abortion was successful and typically includes a pelvic exam and a combination of pregnancy testing and/or ultrasonography. However, the visit adds additional time and cost burdens to women seeking abortion services and clinics. Because of the high success rate of the method, several studies have explored alternate methods of follow-up that would eliminate the need for in-person assessment for all but a small number of women [1–3]. These alternative methods include home pregnancy tests, standardized questionnaires and/or phone- or Internet-based clinician interactions.

Our study focused on the home pregnancy test as a possible replacement for in-person follow-up. Previous studies have shown that serum human chorionic gonadotropin (hCG) measures can determine successful pregnancy termination in medical abortion without the use of sonography [1,2]. Since hCG can also be measured using urine pregnancy tests, an accurate (and easy to interpret) urine test combined with a clinician phone consultation could allow women at home to evaluate their abortion outcomes and return to the clinic only if further attention were warranted [2,4].

To that end, two earlier studies examined the potential of at-home follow-up with urine pregnancy tests. Grossman et al. [5] explored whether urine hCG levels corresponded to serum hCG. Of the 97 women enrolled, there were 5 false negatives, representing women whose urine pregnancy test identified them as having clinically lower hCG levels than

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was actually found with the serum test. The sensitivity and specificity of the urine test to determine a serum level above 1000 mIU/mL was 88.6% and 71.7%, respectively. A second study, by Godfrey et al. [6], examined the correlation of urine hCG testing to serum hCG levels using both low- and high-sensitivity urine pregnancy tests and found that low-sensitivity tests are effective in determining false negatives and could reduce some clinic-based follow-up, but that the high rate of false-positive results would still lead to additional (and possibly unnecessary) testing and/or procedures at follow-up.

In the present studies, we explored the feasibility and acceptability of an at-home semi-quantitative hCG in lieu of clinic-based follow-up 1 week after mifepristone administration. We sought to determine how well the test predicted completion of abortion and to what extent women at home could use it to correctly interpret the results. We hypothesized that if the semi-quantitative pregnancy test could estimate hCG levels with enough accuracy to identify ongoing pregnancy, it could simplify medical abortion care globally.

2. Materials and methods

This clinical study was a 1-year open-label trial. Women presenting for medical abortion at one of the four sites (Stanford University Hospital's OB/GYN clinic, Palo Alto, CA; Planned Parenthood Mar Monte, Sacramento, CA; and two clinics of the Family Planning Associates Medical Group, Limited, Chicago, IL, USA) were invited to join the study. Eligibility for participating women included being 18 years or older, having a pregnancy with gestational age of ≤ 63 days by last menstrual period using ultrasound or clinical assessment, agreeing to return for a follow-up visit, providing an address and/or telephone number for follow-up and being able to consent to study participation. All sites received institutional review board approval to conduct this research, and all participants gave written informed consent.

Study participants were asked to take a semi-quantitative pregnancy test on the day of mifepristone administration to serve as a baseline. Each woman was given one semi-quantitative urine pregnancy test and a sample collection cup to take home. Either first-morning or random urine could be used as an earlier study determined no difference in hCG reading using samples from either time of day (Blumenthal P., personal communication). Women were scheduled to return for a follow-up visit 1 week later. Women were also given written instructions explaining how to use the test and a short questionnaire to complete after using the test at home.

The morning of the follow-up visit, each woman collected a small amount of her urine in the cup which she then used to perform the pregnancy test. Participants were instructed to bring the completed questionnaire and pregnancy test to the follow-up visit. Upon arrival at the clinic, the woman was interviewed about her pregnancy status. A health provider recorded the woman's assessment of her pregnancy status and then completed further assessments using standard clinical means (including any of the following: a physical exam, ultrasound and/or serum hCG); the provider then reviewed the semi-quantitative test result and questionnaire with the woman. The provider used this information to determine the outcome of her abortion. If the health provider found that urine plus clinical testing results were inconclusive or contradictory, the provider conducted a serum hCG measurement at this time. All other standard care for early medical abortion was offered to women as per procedures at each health center.

The clinical study used the dBest® (AmeriTek Inc., Everett, WA, USA) semi-quantitative panel test. The dBest panel test is a one-step immunochromatographic assay to detect hCG in urine with cutoffs of 25, 100, 500, 2000 and 10,000 mIU/mL (Fig. 1). Tests were provided to participants free of charge for use in the study. In normal pregnancies, hCG levels will double every 48–72 h, peaking at 8–11 weeks of pregnancy and then declining for the remainder of the pregnancy. Levels should decrease substantially following a completed abortion [7]. In this study, a pregnancy was considered ongoing if the follow-up hCG reading was the same or higher than the baseline result.

At the same time, we conducted a user comprehension survey to assess women's ability to read and interpret the

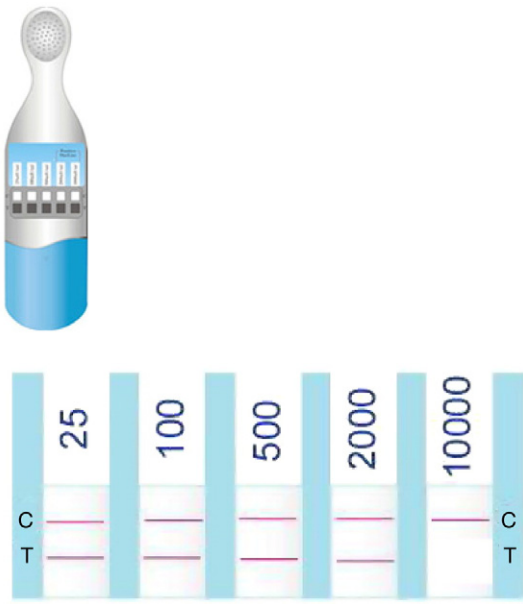

Fig. 1. Images of semi-quantitative pregnancy test used in these studies with reading of 2000 mIU/mL hCG. C: control line. A control line indicates that the test strip has been properly saturated with urine. A control line must appear in all five columns for the test to be considered valid. T: test line. A test line indicates a positive test result. A column with one line (a C line but not a T line) is indicative of a negative test reading. A column consisting of two lines (a C line and a T line) indicates a positive test reading for the specific level of hCG.

Table 1
Clinical trial participant characteristics

	n=490
Age, in years: mean±SD (range)	26±6 (18–45)
Education completed: % (*n*)	
Did not finish HS/receive GED	9.5 (45/473)
High school or GED	49.7 (235/473)
College degree	32.4 (153/473)
Postgraduate degree	8.5 (40/473)
Gestational age, in days: mean±SD (range)[a]	46±7 (33–63)
Participant still thought she was pregnant (or was unsure) prior to taking at-home test: % (*n*)[b]	15.8 (55/348)
Participant had complete medical abortion	92.7 (51/55)
Participant had surgical intervention	7.3 (4/55)

[a] *n*=487.
[b] Data not included for 96 women who were lost to follow-up and 45 women for whom data are not available.

dBest® test. One hundred and eighty-nine clients at three of the four locations (all but Stanford University Hospital), who were not participating in the clinical study and were age 18 years or older, were asked to complete the survey. Using a closed box to randomly draw from, participants completed a questionnaire containing an instruction sheet and a selection of pictorial renderings showing a variety of semi-quantitative pregnancy test results. Survey respondents gave informed consent and received a $10 Starbucks gift card.

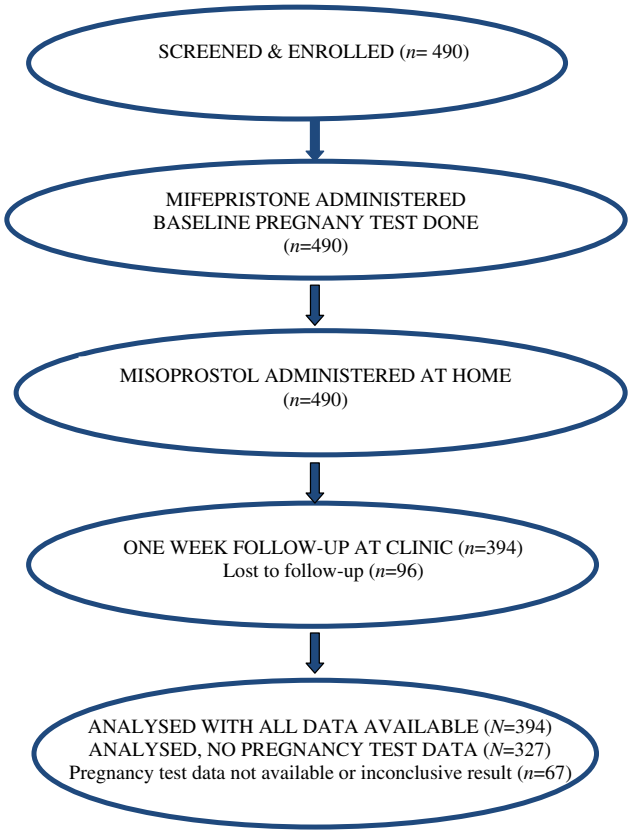

Fig. 2. Flow of clinical trial participants.

Data from both the clinical study and the user comprehension survey were entered into SPSS (Version 15, Chicago, IL, USA). All analyses were conducted using STATA (version 11, College Station, TX, USA). Results are presented as frequencies and means.

3. Results

Between February 2010 and March 2011, 490 women enrolled in the clinical study. The average age of participants was 26 years, and approximately two fifths of them (40.9%) had completed a college degree (153/473) or higher education (40/473) (Table 1). The mean gestational age of their pregnancies was 46 days. Unfortunately, one fifth of participants (19.6%, *n*=96) did not return for follow-up and

Table 2
Outcomes of medical abortion among clinical trial participants: % (*n*)

	n=394
Medical abortion outcome, all participants: % (*n*)[a]	
Success	97.5 (384)
Surgical intervention	2.5 (10)
Persistent nonviable pregnancy or sac	2.0 (8)
Retained products of conception	0.3 (1)
Ongoing pregnancy	0.3 (1)
Medical abortion outcome among women whose at-home pregnancy test signaled need for clinic-based follow-up: % (*n*)	*n*=10
No intervention needed	90.0 (9/10)
Persistent nonviable pregnancy or sac	10.0 (1/10)
Retained products of conception	0.0 (0)
Ongoing pregnancy[b]	0.0 (0)
Medical abortion outcome for women receiving additional interventions at follow-up not signaled by at-home pregnancy test[c]	*n*=6
Persistent nonviable pregnancy or sac, had at-home tests	100.0 (6)
Retained products of conception	0.0 (0)
Ongoing pregnancy	0.0 (0)
Participant correctly understood whether or not the at-home pregnancy test result signaled need for clinic-based follow-up: % (*n*)[d]	58.1 (190/327)
Ease of using at-home test (*n*=349[e])	
Very easy/easy	91.1 (316/347)
Neither easy nor difficult	6.9 (24/347)
Difficult/very difficult	2.0 (7/347)
Provider's explanation helped in test use and comprehension (*n*=349[e])	
Yes	89.5 (306/342)
No	4.7 (16/342)
Don't know	5.8 (20/342)

[a] Data do not include 96 participants who were lost to follow-up.
[b] The one woman with the ongoing pregnancy did not use the pregnancy test at home; therefore, the ongoing pregnancy was not identified at home. The woman did use the test at the clinic at follow-up, and the test identified the ongoing pregnancy.
[c] Three other women receiving surgical intervention did not complete at-home pregnancy test.
[d] Data do not include 67 women for whom data were not available or home test was inconclusive.
[e] Does not include 45 women for whom data were not available.

Table 3
Sensitivity/specificity and positive/negative predictive values of semi-quantitative pregnancy test based on clinical trial client's reading[a] of semi-quantitative pregnancy test: % (*n*) [b,c]

	Ongoing pregnancy	All other outcomes	RR (95% CI)
Test indicated steady or increasing hCG (*n*=11/331)	100.0 (1/1)[b]	3.0 (10/331)	34.6 (18.8–63.8)
Test indicated decreasing hCG (*n*=321/331)	0.0 (0/1)	97.0 (321/331)	
Sensitivity: 100.0%; specificity: 97.0%			
Positive predictive value: 9.1%; negative predictive value: 100.0%			

[a] Client's reading is not available for 60 clients with complete abortion, 1 client with retained products of conception and 1 client with persistent nonviable pregnancy or sac.

[b] The one woman with the ongoing pregnancy did not use the pregnancy test at home; therefore, the ongoing pregnancy was not identified at home. The woman did use the test at the clinic at follow-up, and the test identified the ongoing pregnancy.

[c] Analysis based on client reading of test compared to clinician assessment of abortion status on day of follow-up.

could not be located. Thus, data from 394 women were available for evaluation. Fig. 2 shows the flow of clinical trial participants.

Prior to taking the home pregnancy test, women were asked to note on their home questionnaire whether or not they felt that their abortion was now complete. Around one sixth of participants (*n*=55) were not sure or thought they were still pregnant. Of these women, 51 had a complete abortion, while 4 received a surgical intervention. Of the women for whom outcome data are available (*n*=394), the vast majority (97.5%, *n*=384) had successful abortions, which we defined as an abortion completed without surgical intervention (Table 2).

Ten women had an at-home pregnancy test that signaled the need for clinic-based follow-up as the test showed the same or an increase in hCG compared to baseline (Table 2). Of these, eight women who had no change in hCG, and one who had an increase in hCG required no additional interventions. One additional woman had no change in hCG and was diagnosed with a persistent nonviable pregnancy/sac that was managed surgically. Six additional women with persistent nonviable pregnancies/sacs had home tests which showed a decrease in hCG from baseline to follow-up. These cases probably could have been managed expectantly at home, although they did receive a surgical completion at the clinic at the follow-up appointment. Unfortunately, the one woman with an ongoing pregnancy in this study did not complete her pregnancy test at home. As per protocol, on the morning of her follow-up (and prior to clinical examination), she was asked to use the test at the clinic. The ongoing pregnancy was identified as having a higher hCG reading than at baseline by the pregnancy test used at the clinic and then verified by provider exam. No participants who had a decrease in hCG shown on the test from baseline to follow-up were later identified to have an ongoing pregnancy. We calculated sensitivity and specificity of the test detecting continuing pregnancy versus all other outcomes and found that the sensitivity and the specificity of the semi-quantitative pregnancy test were high [100.0% (*n*=1/1) and 97.0% (*n*=321/331), respectively] (Table 3).

Approximately two thirds of clinical trial participants (58.1%, *n*=190) correctly determined their need to return to the clinic based on the home test reading being the same or higher than their baseline level. Most (91.1%, *n*=316) found the home test to be "very easy" or "easy" to use. In addition, most (89.5%, *n*=306) found that the information provided by the provider ahead of time helped them to use and understand the test at home.

Results from the user comprehension survey are shown on Table 4. The average age of survey respondents was 27 years, and more than two thirds (70.2%, *n*=113/161) had less than a college degree. Most (92.1%, *n*=174/189) were able to read the pregnancy test accurately. Women with less than a college degree were slightly less successful than those with a college degree or higher at correctly reading the test (88.5%, *n*=100/113), and all participants with a college degree or higher read the test correctly. Among those who accurately read the test, close to three quarters (73.6%, *n*=128/174) correctly interpreted the numerical value of the test. This finding differed by education level: 66.0% (*n*=66/100) of women without a college degree and 85.4% (*n*=41/48) of women with a college degree or higher correctly read and interpreted the threshold hCG level of

Table 4
Results of user comprehension survey[a]

	n=189
Age, in years: mean±SD (range)[b]	27±6 (18–54)
Education completed: % (*n*)	
Did not finish HS/receive GED	6.2 (10/161)
High school or GED	64.0 (103/161)
College degree	28.0 (45/161)
Postgraduate degree	1.9 (3/161)
Pregnancy test was matched with correct corresponding image: % (*n*)	92.1 (174/189)
Among women with less than college degree	88.5 (100/113)
Among women with college degree or higher	100.0 (48/48)
Understood numerical value of test: % (*n*)	73.6 (128/174)
Among women with less than college degree	66.0 (66/100)
Among women with college degree or higher	85.4 (41/48)
Instruction sheet helped with interpreting pregnancy test results: % (*n*)	77.2 (132/171)
Test was easy to use: % (*n*)	
Very easy/easy	59.3 (112/189)
Neither easy nor difficult	28.6 (54/189)
Difficult/very difficult	12.2 (23/189)
Woman believes she could use test on her own in the future to determine pregnancy status: % (*n*)	80.7 (138/171)
Among women with less than college degree	79.2 (80/101)
Among women with college degree or higher	82.6 (38/46)

[a] Participants in the user comprehension survey represent a different patient population. These respondents did not participate in the clinical trial.

[b] *n*=188.

2000 mIU/mL or higher that would indicate a need to return for clinic-based follow-up. Approximately three quarters of the survey respondents (77.2%, *n*=132/171) thought that the instruction sheet helped them to interpret the pregnancy test results, and nearly sixty percent (59.3%, *n*=112/189) reported that the pregnancy test was "very easy" or "easy" to use. Four of every five women (80.7%, *n*=138/171) reported that they could use the test by themselves in the future to determine pregnancy status.

4. Discussion

These results demonstrate that this semi-quantitative urine hCG test can be used as a pragmatic indicator of the need for medical abortion clinical follow-up and, based on ease of use, could successfully replace routine mandatory in-person follow-up visits. The vast majority of tests used by participants in the clinical study accurately indicated whether or not each woman needed to return to the clinic for further care. Additionally, the one ongoing pregnancy in the study was successfully identified with the urine test when used at the follow-up visit. However, the programmatic applications of the test still need development. While most women participating in both the clinical trial and the user comprehension survey correctly read their home test, more than half of the participants in the clinical trial reported that they felt that clinic-based follow-up was needed. Upon further exploration with the study team, we have two hypotheses for why this may have occurred. Certainly, we could focus future efforts on improving counseling on how to interpret the test and by simplifying the information sheet given to women. It is also conceivable that the very nature of this clinical study, instructing all women to return for clinic-based follow-up, led to misunderstanding as to how to answer this question and/or whether or not clinic follow-up was necessary.

Using this semi-quantitative pregnancy test as an alternative to standard follow-up procedures could substantially reduce the proportion of medical abortion clients needing to return to the clinic. In our study, 97.5% of women with successful medical abortions did not need additional care and could have avoided an unnecessary follow-up visit, saving time and money for both women and the health care system. Combining the home pregnancy test with a list of clinical signs and symptoms, such as "feeling pregnant" and "bleeding for at least one day," for women to use may further improve the ability for women to self-assess their need to return to the clinic [1,2,4]. Eliminating the need for an extra visit might be especially beneficial for women living in rural areas who travel great distances to access abortion care, as well as for women living in places where abortion is highly stigmatized and/or illegal. To that end, service delivery with home pregnancy tests as a potential replacement to in-person follow-up should be further explored for implementation in health systems globally.

The switch to home-based outcome assessment would also signal a task shifting in health care in the United States and elsewhere. Abortion follow-up would no longer be focused on the skills of the clinician, but rather on the woman herself, with minimal assistance via phone or e-mail by a nurse or midlevel "facilitator." While physicians are legally required to administer abortion drugs in many states, the rest of the process has long excluded physicians as mandatory participants. The introduction of home-based follow-up would push the shift in health care one step further, reducing the participation of any clinician, including midlevel clinicians, in the abortion process. For many clinics, this would ease the burden on staff and reduce overall costs to both the clinic and women. For some facilities, where a charge for a follow-up visit is integral to medical abortion care, there is the potential for reduced revenue for any given procedure if follow-up is conducted from home. However, revenue from such visits is often minimal, and the fact that many women will not return to clinic for follow-up will improve clinic/appointment availability for *new* clients, thus actually enhancing revenues (since new visits are better reimbursed) and improving overall access to service and care.

These new data provide strong evidence that semi-quantitative home pregnancy tests could be highly effective in identifying ongoing pregnancy and the need to return for further care. Next steps should include further development of education and counseling materials so that women can better understand the clinical implications of their home test result and have more confidence in their interpretation of the test. Establishing a phone-in or online protocol for women to discuss the test results with a clinician and/or providing a list of signs and symptoms for self-evaluation may also be important.

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